Risk Assessment Using the PFDA-FMEA Integrated Method

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Miroslav Čička, Renáta Turisová, Darina Čičková

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ABSTRACT

Purpose: The paper aims to introduce risk assessment in new product development as an important activity for a successful new product launch. A practical example is presented to demonstrate the integration of tools Failure Mode and Effect Analysis (FMEA) and Pythagorean Fuzzy Dimensional Analysis (PFDA) at new product development process, which is a machined component.

Methodology/Approach: Individual steps for creating a case study were carried out: create a Subject Matter Expert (SME) team, identify product failure modes, use linguistic values to assess the FMEA, compute and obtain the PFDA-FMEA and determine the product failure modes ranking.

Findings: Minimized uncertainty in the final evaluation of the FMEA and improvement in the decision-making process based on the risks already identified in the new product development process.

Research Limitation/Implication: The PFDA-FMEA method was based on the risk assessment of a machined part development process. Nevertheless, this method can be used for application in many other areas of industry that require high precision in risk analysis.

Originality/Value of paper: The aim of this paper is to reveal a new integrated method in which FMEA, Pythagorean Fuzzy Sets (PFS) and Dimensional Analysis (DA) are coherent in one model.

Category: Case study

Keywords: failure mode and effect analysis; multiple criteria decision making; pythagorean fuzzy sets; dimensional analysis; subject matter expert

1 INTRODUCTION

The rapid development of technologies that fit into the framework of Industry 4.0 bring new threats and new fails. Therefore, a new perspective is also needed on quality assurance in this context. It is particularly visible in demanding industries, which often require perfection in the smallest details and complex performances in difficult conditions, such as metalworking industry. Demands regarding the accuracy of details in the production of parts bring new challenges regarding risk assessment already during product design.

The goal of the research presented in the article is to choose a suitable method of risk analysis, applicable in the design of new components of an engineering product, based on a detailed literature survey, and to verify it on a specific solution.

The literature survey offers several methodologies to support risk analysis in different contexts, including industrial processes, product design or transport. In the publication Tixier et al. (2002), the authors identified and presented 62 different methodologies for the identification, assessment, and classification of risks. This set includes methodologies based on qualitative and quantitative approaches, as well as deterministic and probabilistic approaches. According to the authors, one of the most widely used methods is called FMEA (Failure Mode and Effects Analysis) and enables a qualitative risk analysis using scores represented by deterministic values. In the traditional version of this analysis, potential failure modes are assessed based on factors of severity, occurrence and detection using a numerical scale ranging from 1 to 10. The authors also state that FMEA is a risk analysis tool that is widely used in the manufacturing industry.

According to Yucesan, Gul and Celik (2021), an error is a failure. The author names it as a state of failure to fulfil the desired or intended goal. For a manufacturing environment, this term is defined as a part or component that causes damage to engineering equipment, manufactured products, or plant infrastructure, affects operations, production, and performance, as well as the plant’s brand and reputation. Defective product is one of the main problems that manufacturing companies face. This problem does not only result in a financial loss, but it often also causes a loss of prestige (Boral et al., 2020). For companies to be able to continue operating in a healthy manner and achieve profits in today’s strong competitive environment, it is necessary to increase the quality of production and reduce the number of defective products.

The risk identification process is the most important and time-consuming phase of risk analysis. Threats, probabilities of occurrence, impacts on the goals of the project or company or customer, severity of consequences, mutual links of risks are defined. The meaning of this is critical analysis, detailed investigation and evaluation or revealing activities or steps that are ineffective, reducing or increasing risk management requirements, proposing changes or corrective actions.

2 LITERARY REVIEW

Several methods can be used to evaluate potential failure modes and address their potential consequences, such as:

- Event Tree Analysis (ETA) – Analytical technique used to define potential accident sequences associated with a particular initiating event or set of initiating events (Čepin, 2011);
- Fault Tree Analysis (FTA) – An analytical technique that is used to evaluate the probability of failure, or the reliability of complex systems (Solc et al., 2021);
- Bow Tie Analysis (BTA) – Analytical technique suitable for initial risk analysis to ensure identification of high probability and high consequence events (Ferdous et al., 2012);
- 5WHY – An iterative technique used to investigate the cause-effect relationships underlying a particular problem. The primary goal of the technique is to determine the root cause of an error or problem by repeating the question “Why?”. Each answer forms the basis of the next question (Nagyová et al., 2019);
- FMEA;
- An equally effective quantitative method for risk assessment is the What if? or Hazard and Operability Analysis (HAZOP) – Threat and operability analysis based on the assessment of the probability of threats and the risks arising from them (Cao et al., 2013);
- Among the frequently used qualitative methods that help to refine procedures in detailed risk analysis are, for example, SWOT analysis (Strengths and weaknesses, opportunities, and threats analysis);
- Brainstorming;
- Five Forces (5F) – Industry and risk analysis. The model works with five elements and the essence of the method is forecasting the development of the competitive situation in the industry under investigation based on an estimate of the potential behaviour of subjects and objects operating on the given market (Goyal, 2020);
- Delphi – Prognostic method of group search for a solution. Determination of expert estimate of future development or status using a group of experts (Cao et al., 2013).

2.1 Failure Mode and Effects Analysis – FMEA

FMEA was first used in the 1960s to solve problems in the aerospace and automotive industries (Bowles and Peláez, 1995). Since then, based on the original version, various improvements have been offered, which are developed by sector – for example, FMEA for the development process, FMEA for the service sector, FMEA for production processes.

The FMEA allows to determine the impact of failures or errors on the performance of the system so that measures can be taken to reduce the risk. Each identified risk is numerically classified in the form of a Risk Priority Number (RNP). The risk number RPN is calculated by multiplying parameters severity (S), occurrence (O), detection (D) (Qin, Xi and Pedrycz, 2020). Each parameter takes values between 1 and 10 (1 indicates the lowest value and 10 indicates the highest value). Errors that lead to a high-risk number are critical and are rated as the highest priority. In the final phase, the proposal of measures to reduce the risk number is considered.

Despite the widespread use of FMEA for more than 50 years, this method still has certain limitations, which contributes to the development of new versions by combining it with other techniques (Magalhães and Lima Junior, 2021). One of these limitations lies in the use of deterministic numerical values that do not allow the quantification of uncertain or imprecise measurements inherent in the risk assessment process. According to Yucesan, Gul and Celik (2021), the limitations of FMEA primarily include the inability to deal with indeterminate failure data, subjective risk assessment according to experts, or failure to consider conditionality between individual errors. Additional weaknesses of the FMEA are presented in Tab. 1.

Table 1 – Weaknesses of FMEA

No.	Description	Literary source
1	Giving equal weight to all three factors S, O, D leads to ambiguity. The results may lead to wrong conclusions based on the RPN comparison.	Kumar et al. (2021) Qin, Xi and Pedrycz (2020) Huang et al. (2020)
2	The value from which it is necessary to implement a corrective action is not determined by a standard or another internal company directive.	Dai et al. (2011)
3	The time-consuming and financial cost of the analysis in the case of systems that are composed of many components and contain many functions, or if the analysis is used in the organization for the first time in a complex way of the system.	Boral et al. (2020) Dai et al. (2011)
4	Incorrect assessment of factors S, O, D.	Yucesan, Gul and Celik (2021) Zhang et al. (2020) Kumar et al. (2021)
5	The result of different combinations of S, O, D values for different defects leads to the same RPN.	Kumar et al. (2021) Huang et al. (2020) Liu et al. (2019)

Notes: S, O, D – Severity, Occurrence, Detection; RPN – Risk Priority Number.

Authors Magalhães and Lima Junior (2021) in their publication provide a proposal for the application of FMEA according to the three steps listed in Tab. 2.

In the first step (Step I), brainstorming is carried out and all available information is used on potential failure modes in the system, design or process that is the subject of the analysis. In this way, potential and known failure modes are identified, probable causes are discussed, and the existing means of detecting the causes and failures, if they occur, are discussed. For each identified failure mode, a score related to factors S, O, D is assigned. The last part of Step I is calculating the risk number RPN. In Step II, the values resulting from the RPN calculation for each mode of failure are sorted in descending order. The RPN classification determines the priority level of failure. Experts involved in the analysed process develop and implement action plans to eliminate or mitigate potential causes of priority failures. Finally, in the last step (Step III), the potential failure modes are re-evaluated to verify the effectiveness of the corrective actions taken.

Table 2 – Description of the Steps in the Application of FMEA

Step I	a) Specify the investigated system, design or process.
	b) Create a team of experts.
	c) Define process requirements or individual functions of product components.
	d) Identify process steps. Identify potential or known failure modes.
	e) Analyse and describe the consequences of each type of error and assess their severity.
	f) Investigate and define the probable causes of each failure mode and assess the occurrence of these causes. How often can the cause occur?
	g) Validation of existing detection methods and assessment of the ability to detect failure modes or causes through these sources. Evaluation of the most effective of the controls in the process that can detect the error or the cause of the error.
	h) Calculate the risk number (RPN).
Step II	a) Sort RPN values in descending order. Failure modes with the highest RPN values are considered the most important and will have a higher priority when determining corrective actions.
	b) Develop a corrective or preventive action plan.
Step III	a) Implement the action plan.
	b) Assess the effectiveness of corrective measures by performing a new evaluation of failure modes with respect to factors S, O, D. If the measures were effective, the value of the RPN is expected to decrease in relation to the initial state of this value.

Notes: S, O, D – Severity, Occurrence, Detection; RPN – Risk Priority Number.

The given sequence of steps of the FMEA method in Tab. 2 has been used for many years and has undergone a significant change in recent years. The automotive industry has a significant impact on people’s daily lives worldwide and affects their safety (Mihaliková et al., 2021). Two basic approaches in the automotive industry represented by the AIAG manual (2022) and the VDA manual (2022) have united, and the result is a joint harmonized edition of the FMEA manual, the first edition of the AIAG & VDA FMEA Handbook.

AIAG is a global organization founded in 1982. The goal of the organization is to increase prosperity in the automotive industry by improving business processes and activities that are part of the supply chain (AIAG, 2022). VDA is an association of the automotive industry, which unites more than 620 German companies from this area and its main idea and goal is the research and production of modern, error-free and safe cars (VDA, 2022).

The methodology the AIAG & VDA FMEA Handbook provides a comprehensive guide. It is divided into seven steps for the creation of an FMEA analysis and contains changes in the form itself as well as in the evaluation tables for factors S, O, D. The handbook states the obligation to document the effectiveness of the implemented measures and perhaps the most significant change is the replacement of the risk number RPN with the evaluation factor Action Priority (AP). A seven-step approach to creating an FMEA – harmonized edition is presented in Tab. 3. This approach provides a comprehensive framework for documenting risks in a detailed and precise manner.

Table 3 – Seven-steps Approach to Creating an FMEA – Harmonized Edition

Step	**Description**
Step 1. Planning and preparation	What project?
	Team, tasks
	Identify source FMEA
	Lessons learned
	What project?
Step 2. Structure analysis	Visualize the scope of the analysis
	Process Flow Diagram
	Identification of process steps and substeps
Step 3. Function analysis	Visualization of functions
	Function tree
	Binding requirements to features
	Customer functions (both internal and external)
Step 4. Failure analysis	Creation of the chain Error - Cause and Error - Consequence
	Potential consequences of failures, failures, causes for each function of the process
	Identifying the causes of process failures
	Customer - supplier cooperation
Step 5. Risk analysis	Assigning preventive measures to the causes of failures
	Assigning detection measures to the causes of failures
	Monitoring measures

Step	**Description**
	Safety and legal requirements
	Assessment of importance, frequency and monitoring
Step 6. Optimization	Identification of measures necessary for risk reduction
	Determination of responsibility and deadlines for the introduction of actions
	Implementation, including confirmation of the effectiveness of measures and risk assignment after their implementation
Step 7. Documenting the results	Communication of the analysis results and the conclusions
	Complete documentation

The new approach in the harmonized Edition of FMEA guides the user to reconcile information between individual steps to ensure accuracy and completeness of the analysis. It helps identify and assign priorities to actions designed to prevent risk. It considers factors S, O, D individually, but also in combination with risk-reducing factors. The benefit of the new approach is a more intensive cooperation between the FMEA team, production plant management, customers, and suppliers.

2.2 Advanced Methods of Risk Analysis and Risk Management (MCDM methods)

To add new functions to FMEA, some studies propose a combination of decision models with existing multi-criteria decision-making methods (MCDM). According to Sarkar (2011), multicriteria decision-making is a branch of Operations Research (OR). Decision-making often involves imprecision and vagueness, which can be effectively handled using fuzzy sets and fuzzy decision-making techniques. In recent years, a considerable amount of research has been carried out on the theoretical and application aspects of MCDM and fuzzy MCDM.

According to Karunathilake et al. (2020), multi-criteria decision-making generally follows six steps, which include: (1) problem formulation, (2) requirements identification, (3) goal setting, (4) identification of various alternatives, (5) criteria development and (6) identification and application of decision-making techniques. Various mathematical techniques can be applied to this process, the choice of techniques being made based on the nature of the problem and the level of complexity assigned to the decision-making process. All methods have their pros and cons.

FMEA is considered a robust tool and is one of the most widespread techniques used to identify and assess risks (Kumar et al., 2021). It considers three risk factors at the same time, and in the industrial production sector, where the term “risk” appears frequently, it occupies an important position, which is why the discussion of risk management in the context of FMEA is also important.

Determining and classifying potential failure modes in FMEA is a multifaceted challenge that requires decision-making based on multiple criteria – MCDM (Karunathilake et al., 2020). For this reason, FMEA can be considered a question of multi-criteria decision-making. The reason is the involvement of multiple risk factors, which includes setting priorities and evaluating potential failure modes based on the mentioned three factors S, O, D. Several studies have provided an overview of the application of multi-criteria decision-making techniques in various areas, including, but not limited to energy industry, environment and sustainability, quality management, construction and project management, safety and risk management, etc. OR achieved a relatively higher application (Sarkar, 2011; Karunathilake et al., 2020; Liu et al., 2019).

The MCDM considers the importance of risk factors, breaks down the risk assessment process into different phases and prioritizes potential failure modes through mathematical models. According to a recent literature review by Liu et al. (2019), more than 150 research papers have been published over the past two decades that report the application of multiple-criteria decision-making in the context of FMEA in different scenarios. At a broader level, common MCDM used in FMEA include, but are not limited to, winner-take-all techniques, outranking techniques, pairwise comparison techniques. In addition, various hybrid and multi-factor techniques have been developed to solve FMEA analysis.

In the issue of multi-criteria decision-making the basic components are criteria and alternatives. The various alternatives are evaluated according to established criteria to formulate a comparison of the alternatives. The results can be further improved by assigning weights to different criteria, as the importance can vary greatly between raters. Thus, there may be different levels of importance for the selected criteria from the perspective of different decision makers (Karunathilake et al., 2020). To ensure the reliability of the results, it is important to evaluate the weights assigned to each criterion by different decision makers.

The choice of a multiple-criteria decision-making technique to solve a particular problem may vary depending on the context, thus emphasizing the need to understand decision-making classifications. Multi-criteria decision-making techniques are categorized into: (1) compensatory and non-compensatory, (2) discrete and continuous, and (3) individual and group decision-making. The classification of MCDM based on discrete and continuous data is most often used. (Sabaei, Erkoyuncu and Roy, 2015)

From the point of view of discrete and continuous data, the techniques of MCDM are divided into multi-attribute decision-making (MADM) and multi-objective decision-making (MODM). MADM considers problems in an inherently discrete decision space, and MODM is based on mathematical theory and deals with problems in a continuous decision space. (Tzeng and Huang, 2014)

3 METHODOLOGY

As the machining processes market grows globally, global consumers are demanding new manufacturing technologies and product innovations. As a result, new complex processes and challenges are presented in manufacturing companies during the very development of a new product, making it necessary to overcome new and greater engineering and scientific challenges. Subsequently, however, the risk of not introducing new products to the market increases. For this reason, a risk analysis is needed in the development of a new product so that stakeholders make the right decisions and achieve the expected goals. Current risk analysis tools are not sufficient to cover identified deficiencies in the development of a new product, primarily due to the uncertainty that is present in human decisions. The proposed Pythagorean Fuzzy Dimensional Analysis – Failure Mode and Effects Analysis (PFDA-FMEA) method removes the uncertainty caused by the human factor during the risk analysis using FMEA in the new product development process.

Dimensional analysis (DA) is a technique used in the decision-making process, especially when choosing alternatives of the multi-criteria type. It is an MCDM technique that assumes that there is an optimal solution, better than others. When evaluating, DA compares each alternative with the ideal alternative to create an Index of Similarity, therefore the highest similarity index is selected as the best alternative to the MCDM multi-criteria decision-making problem. (Villa Silva et al., 2019)

Pythagorean Fuzzy Dimensional Analysis (PFDA) is applied in practice even before the FMEA is started. Its important part is the verbal assessment, based on which the results of the analysis are sorted. The advantage of PFDA is that it allows using input data both quantitatively and qualitatively, so that the information is comparable, even if the types of input data are mixed.

According to García-Aguirre et al. (2021a), the risk evaluation in PFDA compared to the conventional FMEA method is at a more advanced level, while the ambiguity of subjective human judgment is eliminated by applying Pythagorean Fuzzy Sets (PFS).

The basic concept of PFS, which are also used in the case study, is presented through the following definitions (Yager, 2013; Cao et al., 2013; García-Aguirre et al., 2021b).

Definition 1: if X represents the macroworld of considered elements, then the Pythagorean Fuzzy set P in X is given by the eq. 1:

$$P = \{\langle x, \mu_p(x),\ v_p(x)\rangle \mid x \in X\}, \tag{1}$$

where $\mu_p(x): X \to [0, 1]$ defines the degree of membership. Consequently, $v_p(x): X \to [0, 1]$ defines the degree of non-membership of element x, where $x \in X$ in P.

Definition 2: for any Pythagorean Fuzzy set $p = (\mu, v)$, p is defined as follows (eq. 2):

$$s(p) = (\mu)^2 - (v)^2, \tag{2}$$

where $s(p) \in [-1, 1]$.

According to Villa Silva et al. (2019), PFS and DA are combined into one equation in order to solve a multi-criteria decision-making problem (eq. 3):

$$PFIS_i(\omega_1^i, \omega_2^i, \dots, \omega_m^i) = \left(\prod_{k=1}^{n} \left(\mu_{\varepsilon_j^i}\right)^{T_j}, \sqrt{1 - \prod_{k=1}^{n} \left(1 - \left(v_{\varepsilon_j^i}\right)^2\right)^{T_j}} \right), \tag{3}$$

where $PFIS_i$ = Pythagorean Fuzzy Similarity Index, for $i = 1, 2, \dots, m$; ω = Pythagorean Fuzzy set; μ = assigned value of the membership function; v = assigned value of the non-member function; T_j = weight assigned to each expert, for $j = 1, 2, \dots, m, k = 1, 2, \dots, n$, a ε = macroworld of considered elements where $T_j \in [0, 1]$ and index i is defined by the Pythagorean Fuzzy set.

According to García-Aguirre et al. (2021b), the goal of the PFDA-FMEA method is to minimize uncertainty in the final evaluation of the FMEA and thus improve the decision-making process based on the risks already identified in the product design process. The method uses FMEA as a basis for collecting potential failure modes through Subject Matter Experts (SME) on the given issue, and only then is the PFDA method applied. The proposed PFDA-FMEA method is generalized in seven steps, presented in Fig. 1.

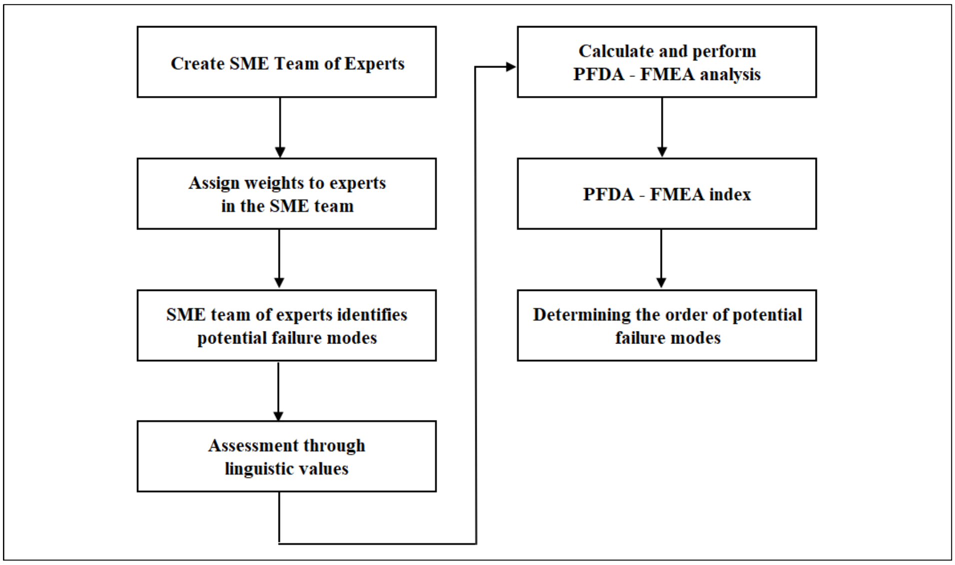

Figure 1 – Methodology of the PFDA-FMEA Approach

Step 1: Create SME team of experts on the given issue. Depending on the product/process being assessed, a group of n experts is created for the given issue.

Step 2: Assignment of weights to experts in the SME team. After the creation of the SME team, each of the experts is assigned a weight; generally: the higher the assigned value, the more important the expert's decision is for the analysis.

Step 3: The SME team of experts identifies potential failure modes and jointly determines the main internal and external characteristics that directly or indirectly affect the analysed product/ process.

Step 4: Assessment through linguistic values. Potential failure modes are evaluated by each expert independently and based on their own experience in the given field. The SME team of experts collects and defines the main areas of impact on the product/process and assigns member and non-member functions based on experience in each area of the analysed product/process.

Step 5: Calculate and perform PFDA-FMEA analysis. The results obtained in the previous step (Step 4) are used for the application of PFDA analysis according to eq. 3, subsequently using eq. 2 the values are defuzzified and the values of PFDA-FMEA analysis are obtained.

Step 6: The value of the PFDA-FMEA index is given by the mathematical calculation of the values S, O, D.

Step 7: Determining the order of potential failure modes. The results are ranked to identify the risks of potential failure modes and to support the decision to be made.

4 CASE STUDY

The company registers questions regarding the identification of risks in the design of a new component, the visualization of risks in specific areas and phases of the project, and indecision in the number and composition of interested parties who are responsible for effective risk assessment.

The proposed PFDA-FMEA method in the case study, which is based on the design of a machine part, uses FMEA analysis as the first step. FMEA helps collect and organize the main potential failure modes in the design phase of the part through the SME team of experts. The SME team of experts consists of a product designer, process engineer and quality engineer who deal with the design and development of parts for the engineering industry, managing the production preparation process and ensuring and improving the quality of production within the plant.

During the design phase of a machine part, risk analysis and assessment is required to avoid product failures and to complete the part design on time and within customer requirements. PFDA-FMEA helps to get a clear overview of the impact of risks associated with the product design process and helps to make the right decisions about where to use what kinds of resources to avoid the potential impact of the identified risks.

Subsequently, the PFDA is applied, the purpose of which is to minimize uncertainty in human decision-making when classifying factors S, O, D.

Step 1: Creation of an SME team of experts. Tab. 3 presents a group of three experts who are labelled as SME1, SME2, SME3. SME experts analysed a machine part named *Wheel axle 022-09-005* (Fig. 2). The wheel axle is a stationary machine part that helps to transmit machine movement.

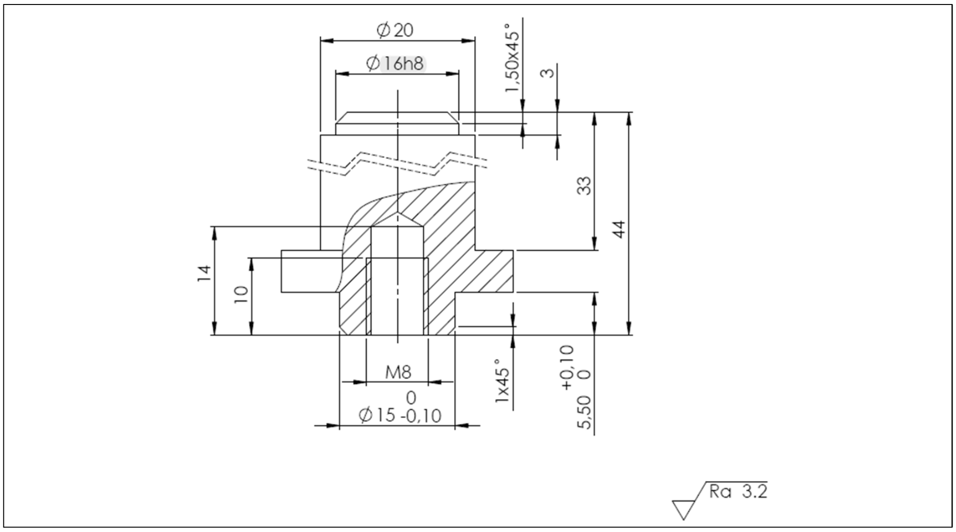

Figure 2 – Wheel Axle 022-09-005 (ICS Ice Cleaning Systems Slovakia)

Step 2: Assigning weights to experts. The weight is assigned to each expert depending on his experience and knowledge in the researched area (Tab. 4). To comply with the condition of eq. 3, that the total weight assigned to experts has a value in the range of 0 to 1, in this case study each SME expert is assigned the same weight (1/3), since the degree of expertise of each SME is in the analysed issue the same.

Table 4 – SME Team of Experts

No.	**Area of Expertise**	**Job Title - Level of Education**	**Number of years of experience in the area of expertise**	**Weight assigned**	**Weight coefficient**
SME1	Design of a machine part; processing of the 3D model of the part; creation of technical documentation; understanding customer requirements.	Product Designer - Bc.	4	1/3	0.33

No.	Area of Expertise	Job Title - Level of Education	Number of years of experience in the area of expertise	Weight assigned	Weight coefficient
SME2	Responsibility for the correct setting of production processes; creation of the methodology of production procedures, technical documentation and the setting of control mechanisms in order to achieve the most efficient production cycle.	Process Engineer - Ing.	5	1/3	0.33
SME3	Planning, developing, implementing, and maintaining product quality improvement and cost reduction processes; ensuring the quality of delivery of purchased parts; introduction of appropriate measurement and sampling techniques and procedures.	Quality Engineer - Ing.	8	1/3	0.33

Notes: SME – Subject Matter Experts, Bc. – Bachelor of Design in Product Design; Ing. – Master in Quality Management/ Master of Engineering.

Step 3: A team of SME experts identifies potential failure modes of the machine part. Experts in the design phase of a machine part suggest potential failure modes that have a direct or indirect impact on the part design process. For this purpose, a group of experts created and agreed on a list of 17 potential failure modes listed in Tab. 5.

Table 5 – Potential Failure Modes in the Design of a Machine Part Identified by the SME Team of Experts

Area	Potential Failure Modes (PFM) – Code	Potential Failure Modes
T	PFM1	Lack of stock of material for the start of production
Q	PFM2	Errors in the technical specification of the product
T	PFM3	The design of the product is visually unbalanced
T	PFM4	Long delivery time of raw material for production (steel)
T	PFM5	Last minute design changes
Q	PFM6	Insufficient technical performance of the product
Q	PFM7	Failure of product pilot testing
T	PFM8	Insufficient production capacity of the production plant
B	PFM9	Errors in the initial samples for the customer
B	PFM10	Outdated technology for product development
B	PFM11	Environmental burden during production not considered
I	PFM12	Lack of experts for product development

Area	**Potential Failure Modes (PFM) – Code**	**Potential Failure Modes**
Q	PFM13	Low quality of the input raw material to produce the product
I	PFM14	Changes in the customer's requirements for the final product
I	PFM15	New (untested) technologies in the production process
B	PFM16	The product exceeds the specified production costs
B	PFM17	The production plant is not ready to start production

Notes: I – innovation (a new idea, design, product or method, or development or use of a new idea, design, product or method); Q – quality (the degree to which an object or entity, e.g., process, product, or service satisfies a specified set of attributes or requirements); T – time (time period or time section), B – budget (an estimation of revenue and expenses over a specified future period of time).

Step 4: Perform FMEA using linguistic values. A team of SME used the list of linguistic values listed in Tab. 5, which include the following areas: innovation (I), quality (Q), time (T), budget (B). Each of these areas is divided into levels of influence: low (L), neutral (N), high (H), and a team of SME assigned individual values and levels their member and non-member functions.

Table 6 – Linguistic Values for PFDA, Assignment of Member and Non-Member Functions

Linguistic values and their abbreviations	**Membership functions ($\mu\varepsilon$)**	**Non-membership functions ($\vartheta\varepsilon$)**
Low Impact on Innovation (LI)	0.07	0.98
Neutral Impact on Innovation (NI)	0.47	0.49
High Impact on Innovation (HI)	0.98	0.10
Low Impact on Quality (LQ)	0.15	0.95
Neutral Impact on Quality (NQ)	0.50	0.55
High Impact Quality (HQ)	0.80	0.20
Low Impact on Time (LT)	0.35	0.85
Neutral Effect on Time (NT)	0.45	0.55
High Impact on Time (HT)	0.95	0.10
Low Budget Impact (LB)	0.20	0.75
Neutral impact on the budget (NB)	0.45	0.45
High Budget Impact (HB)	0.75	0.25

Linguistic values were subsequently used to evaluate the FMEA, which is presented in Tab. 7. The team of experts used linguistic values to define S, O and D. This step simulates the manipulation of uncertainty in the evaluation process by human judgment. For practical reasons are in Tab. 6 presented only abbreviations of linguistic values, e.g. "Low Quality Impact" (LQ).

Table 7 – Assessment of the FMEA by a Team of SME through Linguistic Values

PFM code	**Severity**			**Occurrence**			**Detection**		
	SME1	SME2	SME3	SME1	SME2	SME3	SME1	SME2	SME3
PFM1	HT	NT	NT	NT	NT	LT	HT	NT	NT
PFM2	NQ	NQ	LQ	NQ	NQ	LQ	HQ	NQ	NQ
PFM3	NT	LT	NT	NT	NT	LT	HT	NT	NT
PFM4	HT	NT	HT	LT	LT	NT	LT	NT	LT
PFM5	NT	HT	HT	NT	NT	NT	NT	NT	NT
PFM6	HQ	NQ	HQ	NQ	NQ	LQ	HQ	NQ	NQ
PFM7	NQ	NQ	LQ	NQ	LQ	LQ	NQ	NQ	LQ
PFM8	NT	LT	NT	LT	LT	LT	NT	LT	NT
PFM9	NB	NT	LB	NT	NT	LB	LB	LB	LB
PFM10	NB	NB	LB	NB	NB	LB	LB	LB	LB
PFM11	NB	LB	NB	LT	NB	LB	LB	NB	LB
PFM12	NI	LI	NI	LI	NI	LI	LI	NI	LI
PFM13	LQ	LQ	LQ	NQ	LQ	NQ	NQ	NQ	NQ
PFM14	HI	NI	HI	NI	NI	LI	HI	NI	NI
PFM15	LI	LI	NI	NI	NI	NI	NI	LI	LI
PFM16	LB	NB	LB	NB	LB	LB	LB	LB	NB
PFM17	HB	NB	NB	NB	NB	LB	NB	LB	NB

Notes: PFM – Potential Failure Modes; SME – Subject Matter Experts.

Step 5: Calculate and perform PFDA-FMEA. PFDA is applied through eq.3; subsequently, eq. 2 (both given in chapter Methodology) is used to defuzzify fuzzy values and obtain data. The calculation results obtained through the PFDA-FMEA are presented in Tab. 8 and include the calculation results for S, O, D.

Table 8 – PFDA-FMEA Results for Values S, O, D

PFM	**Severity**	**Occurrence**	**Detection**
PFM1	0.1171	-0.3157	0.1171
PFM2	-0.5260	-0.5260	0.1179
PFM3	-0.3157	-0.3157	0.1171
PFM4	0.4293	-0.4779	-0.4779
PFM5	0.4293	-0.1000	-0.1000
PFM6	0.3309	-0.5260	0.1179

PFM	**Severity**	**Occurrence**	**Detection**
PFM7	-0.5260	-0.7619	-0.5260
PFM8	-0.3157	-0.6000	-0.3157
PFM9	-0.2577	-0.2850	-0.5225
PFM10	-0.2292	-0.2292	-0.5225
PFM11	-0.2292	-0.3969	-0.3969
PFM12	-0.6541	-0.8765	-0.8765
PFM13	-0.8800	-0.5260	-0.0525
PFM14	0.4949	-0.6541	0.1905
PFM15	-0.8765	-0.0192	-0.8765
PFM16	-0.3969	-0.3969	-0.3969
PFM17	0.1263	-0.2292	-0.2292

Notes: PFM – Potential Failure Modes; SME – Subject Matter Experts.

An example of calculating the S value for line number 1 in Tab. 8. The values used in the calculation are based on the values in Tab. 9.

Table 9 – Numerical Values of PFM 1 Used in the PFDA-FMEA

PFM1	**Severity**			**Occurrence**			**Detection**		
	HT	NT	NT	NT	NT	LT	HT	NT	NT
$(\mu\varepsilon)$	0.95	0.45	0.45	0.45	0.45	0.35	0.95	0.45	0.45
$(\vartheta\varepsilon)$	0.10	0.55	0.55	0.55	0.55	0.85	0.10	0.55	0.55

Notes: PFM – Potential Failure Modes; HT – High Impact on Time; NT – Neutral Effect on Time; LT – Low Impact on Time.

For calculating membership values $(\mu\varepsilon)$ for S – severity, the first part of eq. 3 was used:

$$PFIS_3 = (0.95)^{\frac{1}{3}} \cdot (0.45)^{\frac{1}{3}} \cdot (0.45)^{\frac{1}{3}} = 0.5773. \tag{4}$$

For calculating non-membership values $(\vartheta\varepsilon)$, the second part of eq. 3 was used:

$$PFIS_3 = \sqrt{1 - \left\{[1-(0.10)^2]^{\frac{1}{3}} \cdot [1-(0.55)^2]^{\frac{1}{3}} \cdot [1-(0.55)^2]^{\frac{1}{3}}\right\}} = \\ \sqrt{1 - \left[(1-0.01)^{\frac{1}{3}} \cdot (1-0.3025)^{\frac{1}{3}} \cdot (1-0.3025)^{\frac{1}{3}}\right]} = \\ \sqrt{1-(0.7839)} = 0.4649. \tag{5}$$

To defuzzify the values, eq. 2 was used:

$$s(p) = (0.5773)^2 - (0.4649)^2 = 0.1171 \tag{6}$$

Step 6: PFDA-FMEA index. Values listed in Tab. 7 were used to calculate the PFDA-FMEA Index (S×O×D). The results are presented in Tab. 9 and potential failure modes are listed according to the value of the risk number.

Table 10 – PFDA-FMEA Results and Risk Assessment

Potential Failure Modes (PFM) – code	**PFDA-FMEA Index**	**PFDA-FMEA ranking according to the value of the risk number**
PFM1	-0.0043	6
PFM2	0.0326	2
PFM3	0.0117	3
PFM4	**0.0980**	**1**
PFM5	0.0043	5
PFM6	-0.0205	8
PFM7	-0.2108	16
PFM8	-0.0598	13
PFM9	-0.0384	12
PFM10	-0.0275	10
PFM11	-0.0361	11
PFM12	-0.5026	17
PFM13	-0.0243	9
PFM14	-0.0617	14
PFM15	-0.0148	7
PFM16	-0.0625	15
PFM17	0.0066	4

Step 7: Determine the ranking of potential failure modes. The results are sorted to identify those potential failure modes for which action needs to be taken. This assessment of potential failure modes reveals the future scenario to be considered when assessing risk in the design of a machine component. In this sense, PFM4 – Long delivery time of raw material for production (steel) represents the greatest risk because it has the highest index number.

It is evident from the PFDA-FMEA ranking of potential failure modes listed in Tab. 10 that the lowest number represents the PFM with the highest risk.

5 DISCUSSION AND CONCLUSION

FMEA is an advanced tool that can be defined as simple and intuitive providing added value to the risk management process (Juhaszova, 2013). Based on the literature survey in the introduction chapter, it can be concluded that the application of FMEA in risk assessment is criticized by the professional public mainly because of the uncertainty present in risk classification. According to Turisova and Kadarova (2015), the FMEA method is usually developed by a team of experts. Analysis means team responsibility, where individual problems arising are solved by consensus, i.e. that the opinion of the most active members is accepted.

In the case study, the proposed PFDA-FMEA method has the advantage over the conventional FMEA that it compensates the possible uncertainty with linguistic values and their influence levels. Although there are currently various approaches proposed to improve FMEA, for example the harmonized edition of AIAG & VDA FMEA (Česká společnost pro jakost, 2019) focused not on the product of factors S, O, D but on the priority for action especially from the point of view of the severity of the impacts on the production plant, customer or final consumer. Unlike the conventional FMEA method, the proposed PFDA-FMEA method combines PFS, dimensional analysis and FMEA itself, thereby improving the current FMEA methodology.

Risk identification is the process of finding, recognizing, and describing risks. Risk analysis is a process to understand the nature of risk and to determine the level of risk, that is – the magnitude of a risk or combination of risks expressed in terms of the combination of consequences and their likelihood (Lengyel, Zgodavová and Bober, 2012). Fig. 3 shows the current state of risk assessment in the design of a machine component in company ICS ICE Cleaning Systems, which is complexly organized and risk identification in this case is quite difficult. In comparison with the proposed state, which results from the case study, it is clear how it is possible to proceed in the future in the identification of potential failures modes and which areas can be affected or are the most critical.

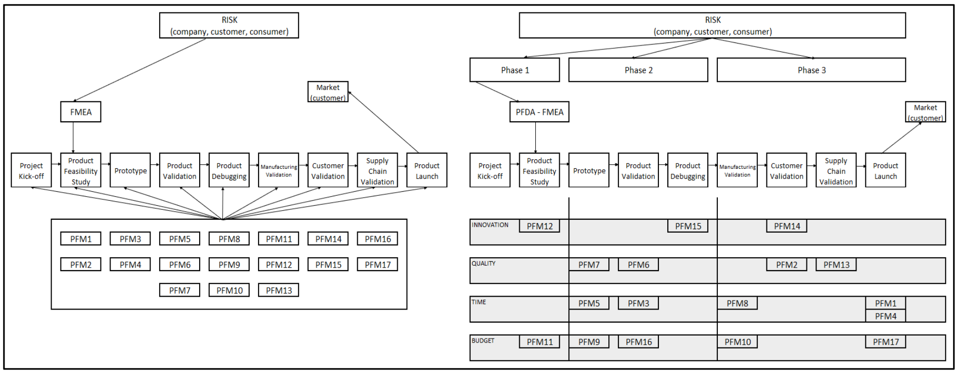

Figure 3 – Comparison: Risk Assessment Before and After the Introduction of PFDA-FMEA in the Company

This visualization makes it possible to assign resources to those areas where they are needed to mitigate the identified risks. Areas (quality, innovation, time, budget) help classify the goals to be achieved.

Fig. 4 shows a comparison of potential failure modes against the values for severity, occurrence and detection, where it is clear that PFM4, PFM5, PFM6 and PFM14 had the highest values for the severity of impacts.

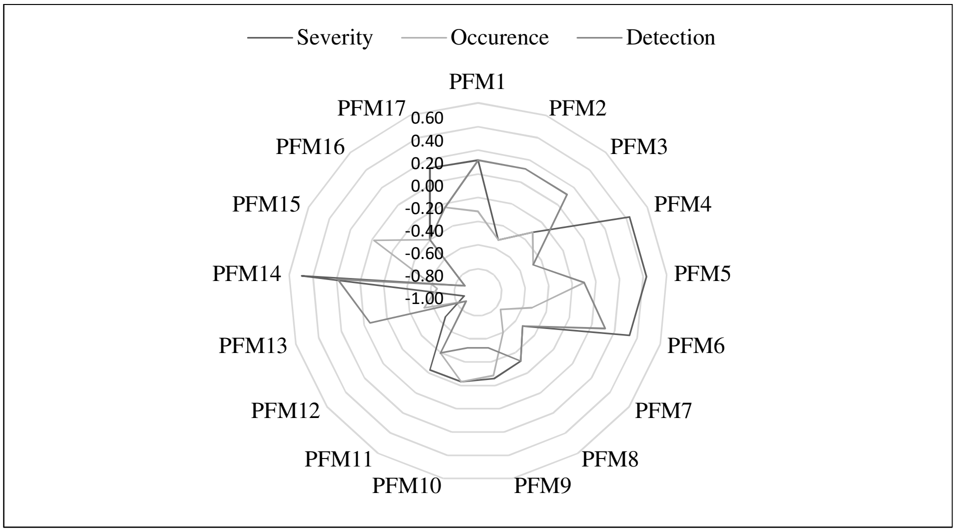

Figure 4 – Comparison: PFM and Values of PFDA-FMEA for S, O, D

After reviewing the literature there is room for improvement in the topic of risk analysis in the new product design process, but the presented integrated PFDA-FMEA method overcomes the main identified shortcomings and provides an advanced solution for risk assessment methods. The main benefits of the method include:

1. Elimination of uncertainty in human judgment in risk assessment due to the diversity of opinions and views in the cross-sectional team;
2. Determining the sequence of risks (allows to focus on resources at the right time in the right area);
3. A visual way of identifying risks (allows to focus on the area where the risk may occur);
4. Possible implementation of the method in various areas of industry (nanotechnology, medicine, ...) where high precision in risk assessment is required.

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ABOUT AUTHORS

Miroslav Čička0000-0002-6585-2429 (M.Č.) – external PhD. Student, Department of Safety and Production Quality, Faculty of Mechanical Engineering, Technical University of Kosice, Kosice, Slovakia. e-mail: mirko.cicka@gmail.com.

Renáta Turisová0000-0003-3333-0914 (R.T.) – Assoc. Prof., Department of Safety and Production Quality, Faculty of Mechanical Engineering, Technical University of Kosice, Košice, Slovakia, e-mail: renata.turisova@tuke.sk.

Darina Čičková0000-0003-4273-5358 (D.Č.) – External Interim Consultant for a company specializing in the development and manufacturing of aluminum components for powertrain and body structure applications in the automotive industry, Slovakia, e-mail: cickova.dari@gmail.com.

AUTHOR CONTRIBUTIONS

Conceptualization, M.Č. and D.Č.; Methodology, R.T.; Investigation, M.Č. and D.Č.; Original draft preparation, M.Č.; Review and editing, D.Č.; Supervision, R.T.

CONFLICTS OF INTEREST

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